

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Development, implementation and evaluation of an intervention to improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Protocol summary

Study aim

Improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Design

Randomised trial with control group ,without blinded, design for 300 students, Simple cluster randomization

Settings and conduct

This research has 3 phases, 4 sub-studies and 6 steps which on the students of the 4th, 5th and 6th grade of Baneh city in control and intervention groups will be done. The intervention phase of the study includes the allocation of the target group in two groups of intervention and control, which In the intervention group will be done the educational intervention.

Participants/Inclusion and exclusion criteria

Arrival conditions: 1- Education at the 4th, 5th or 6th grade elementary level 2- Residents of Baneh City 3- Having consent from the participants and their parents
Non-arrival conditions: 1- Being over 12 years old and less than 10 years 2. Not having consent form

Intervention groups

The intervention group: Students from the 4th, 5th and 6th grade students studying and residing in Baneh, with the consent form to receive theoretical-based educational interventions to improve nutritional literacy. The control group: They have the same conditions as the intervention group

Main outcome variables

1- Promoting food and nutrition literacy (analytical, interactive, and functional) 2- Modify the weight of participants 3. Increased participants' height

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151208025431N5**

Registration date: **2018-07-14, 1397/04/23**

Registration timing: **prospective**

Last update: **2018-07-14, 1397/04/23**

Update count: **0**

Registration date

2018-07-14, 1397/04/23

Registrant information

Name

Elham Shakibazadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 4293 3210

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-10-02, 1397/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development, implementation and evaluation of an

intervention to improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Public title

Improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

10-12 years-old elementary school children of Baneh City which schooling during the study course.

Exclusion criteria:

Elementary students over 12 years of age or under 10 years of age

Age

From **10 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Random Cluster Lottery: Randomization is done using a simple random clustering method whose classes include four regions of the north, south, east and west of the city of Baneh and in each class each school is considered as a cluster, which these clusters, four schools (clusters) will be selected for each region which has two schools (one for boys and one for girls) for the intervention group and two schools (one for boys and one for girls) will also be for the control group. In each district there are 4 schools and in total in the whole city of Baneh, 16 schools will be selected. Given that the total number of non-profit primary schools is 4 schools whether or not they choose to influence the outcome of the study will not be effective, therefore to prevent their potential confounding effect, selection of the above schools abandoned and all elementary state schools that include 48 schools will be selected. excluded from the selection of these schools and all elementary state schools that include 48 School will be selected.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Designing a study based on intervention mapping approach which has six steps.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of tehran University of Medical Sciences

Street address

Poursina Street, Quds Ave, Keshavarz Boulevard, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-06-13, 1397/03/23

Ethics committee reference number

IR.TUMS.SPH.REC.1397.031

Health conditions studied**1****Description of health condition studied**

Development, implementation and evaluation of an intervention to improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

ICD-10 code

Z55.8

ICD-10 code description

Other problems related to education and literacy
Inadequate teaching

Primary outcomes**1****Description**

Improve food and nutrition literacy among 10-12 years-old school children of Baneh using Intervention Mapping approach

Timepoint

Measuring food and nutrition literacy at the beginning of the study ,3 and 6 months after the intervention .

Method of measurement

Standard questionnaire

2**Description**

Weight

Timepoint

Measuring weight at the beginning of the study ,3 and 6 months after the intervention .

Method of measurement

Digital Sohenle Scale with 100g accuracy

3**Description**

Height

Timepoint

Measuring height at the beginning of the study ,3 and 6 months after the intervention .

Method of measurement

Strip meter

Secondary outcomes**1****Description**

Improve food and nutrition literacy among 10-12 years-old school children

Timepoint

0,3&6 Month

Method of measurement

Questionnaire

2**Description**

Weight

Timepoint

0,3&6 Month

Method of measurement

Digital Sohenle Scale with 100g accuracy

3**Description**

Height

Timepoint

0,3&6 Month

Method of measurement

Strip meter

Intervention groups**1****Description**

Intervention group: Theory-based interventions based on SCT theory and the needs assessments that have been taken before the study begins and the level of food and nutrition literacy, weight and height before intervention and 3 and 6 months after the intervention.

Category

N/A

2**Description**

Control group: The control group will not intervene and only level of food and nutrition Literacy , weight and height were measured baseline and 3, 6 months after

the intervention.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Elementary schools in Baneh city

Full name of responsible person

Mohammad Ahmadpour

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No 76835,Taban Alley10,Shahid Motahari St

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

School of Public Health, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
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Ph.D student
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available